

Remarks

Claims 31-43 and 50-63 are pending in the subject application. Applicant acknowledges the Examiner's withdrawal of the finality of the rejections in the Office Action dated February 8, 2005. Applicant also gratefully acknowledges the Examiner's indication that claims 36-43 are free of the prior art. By this Amendment, Applicant has amended claim 31. Support for the amendment can be found throughout the subject specification. Entry and consideration of the amendment presented herein is respectfully requested. Accordingly, claims 31-43 and 50-63 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claim 37 is rejected under 35 USC §112, first paragraph, as nonenabled by the subject specification. The Examiner asserts that FIV strains *Dix*, *UK8*, *Aom1*, *Aom2*, and *Pet* are not readily available to the public and, therefore, the subject specification does not enable a person of ordinary skill in the art to practice the claimed invention. Applicant respectfully traverses this ground of rejection.

Applicant respectfully asserts that the subject specification does enable the claimed invention. The *Petaluma* strain of FIV (abbreviated FIV_{Pet}) has been deposited with American Type Culture Collection (ATCC) under ATCC accession number VR-1312. Applicant respectfully asserts that the other FIV strains recited in the claim are available. Sequence information for FIV strain *Dixon* is available at Genbank accession number L00608. Sequence information for the *UK8* and *Aomori* strains of FIV is also available at Genbank. Thus, a person of ordinary skill in the art can readily make and use the FIV strains recited in the claim. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

Claims 31-35, 50, 51, 53-63 are rejected under 35 USC §103(a) as obvious over Yamamoto *et al.* (U.S. Patent No. 5,275,813) in view of Sodora *et al.* (1994) and Zagury *et al.* (International Publication No. WO 92/00098). In addition, Claim 52 is rejected under 35 USC §103(a) as obvious over Yamamoto *et al.* (U.S. Patent No. 5,275,813) in view of Sodora *et al.* (1994) and Zagury *et al.* (International Publication No. WO 92/00098) and further in view of Yamamoto *et al.* (1993). The Sodora *et al.* reference is cited as teaching various subtypes of FIV. The Zagury *et al.* reference is cited as teaching a multiple HIV virus strain composition and the use thereof. The Examiner asserts that an ordinarily skilled artisan would have had a reasonable expectation of success that an FIV

multi-subtype vaccine would work because Zagury *et al.* taught that a cocktail of peptide sequences from several HIV strains induce a “broad immune response.” The Yamamoto *et al.* patent is cited as teaching vaccination of cats with FIV and that further FIV strains will be useful for producing immunogens. The Examiner concludes it would have been obvious to use multiple subtypes of FIV for vaccination with the method of the Yamamoto *et al.* patent. Applicant respectfully traverses these grounds of rejection.

Applicant respectfully asserts that the claimed invention is not obvious over the cited references, regardless of whether the cited references are taken alone or in combination. By this Amendment, Applicant has amended claim 31 to recite that the vaccine composition induces a **protective** immune response against FIV infection. There is nothing in the cited references that would have led the ordinarily skilled artisan to have expected that the use of a multi-subtype FIV vaccine composition of the present invention could provide the vaccinated animal with a protective immune response against infection by FIV.

In making the rejection, the Examiner acknowledges that the Yamamoto *et al.* patent does not teach the use of a plurality of FIV subtypes for use in a vaccine or in a method for eliciting an immune response against FIV infection. The Examiner relies on the Zagury *et al.* reference to provide the requisite motivation and reasonable expectation of success in obtaining the claimed invention. Assuming, *arguendo*, that the cited references did suggest trying a plurality of FIV subtypes in a vaccine, Applicant respectfully asserts that the ordinarily skilled artisan would not have had the requisite “reasonable expectation of success.” At best, the ordinarily skilled artisan might expect that a multi-subtype vaccine would result in the generation of some immune response, although not necessarily a protective response, against homologous FIV used in the vaccine composition or, perhaps, even heterologous FIV strains that were closely related to the strains used in the vaccine composition. However, Applicant respectfully asserts that the ordinarily skilled artisan would not have expected that a vaccine composition of the present invention would provide a protective immune response, particularly against FIV infection by less closely related heterologous strains, including strains that are of a subtype not present in the vaccine composition. Moreover, an ordinarily skilled artisan would not have expected that a vaccine composition of the present invention would provide a protective immune response against a subtype of FIV that was not present

as an immunogen in the vaccine. Applicant also respectfully notes that the multi-subtype vaccine compositions of the present invention generate antibody titer levels against FIV antigens that are higher in comparison to the antibody titer level obtained using a single-subtype FIV vaccine composition. Additionally, multi-subtype vaccine compositions of the present invention provide greater levels of protection against infection than single-subtype vaccines when the vaccinated animal is challenged with FIV virus.

Applicant respectfully asserts that the references cited by the Examiner under the §103 rejections do not teach or suggest the claimed invention. The claimed vaccine composition of the subject invention provides for unexpected protection and immunogenicity against FIV infection. Accordingly, reconsideration and withdrawal of the rejections under 35 USC §103(a) is respectfully requested.

Claims 37, 42, and 43 are rejected for “obviousness type” double patenting over claims 2 and 4 of U.S. Patent No. 5,846,825. Applicant acknowledges that a terminal disclaimer can be filed to overcome this rejection. Accordingly, upon the Examiner’s indication that the subject application is in condition for allowance but for the “obviousness type” double patenting rejection, a terminal disclaimer will be filed or other appropriate action will be taken.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicant’s agreement with or acquiescence in the Examiner’s position.

In view of the foregoing remarks and amendments to the claims, Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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